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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,583	02/08/2007	Sayoko Matsumoto	09812.0126	3961

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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	
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05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,583	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	STEPHEN KAPUSHOC	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending.

Claims 5-10 remain withdrawn from examination as detailed in the previous Office Action.

Claims 1-4 and 11-13 are examined on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/02/2009 has been entered.

This Office Action is in reply to Applicants' correspondence of 02/02/2009 and the request for continued examination of 04/08/2009.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put this application in condition for allowance.

This Action is **NON-FINAL**.

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Claim Rejections - 35 USC § 103

1. Claims 1-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namasivayam et al (2002) (as cited on the IDS of 02/12/2008) in view of Lee et al (2002) (citation 'U' on PTO-892 of 04/01/2008).

Namasivayam et al teaches methods of stretching nucleic acid molecules. Relevant to the limitations of independent claim 1, the reference teaches: providing a reaction detecting section including a first electrode, a seconded electrode, and a reaction well sandwiched between the electrodes (Fig 7a); a reaction system with a solution of pH 5 to 11 (p.3380, left col., lns.9-26). Relevant to the surface are requirements of the electrodes as recited in the claims, the reference teaches an electrode configuration comprising a straight electrodes adjacent to a flattened 5-μm tip as an active electrode (p.3383 left col.-right col.), thus providing a first electrode (the 5-μm tip) having a surface area smaller that that of the second electrode (Fig 7d; Fig 9). The reference further teaches that without application of an electric current, the nucleic acid is in a coiled form, thus teaching adding a nucleic acid in a coil form (e.g. legends of Figs 5, 6, and 9). The reference teaches applying an ac voltage of high frequency to the electrodes, which forms an electric field and stretches the nucleic acid, and migration of the nucleic acid toward the first electrode (e.g.: p.3380 – Application of electric fields; Fig. 9).

Relevant to the limitations of claim 2, Namasivayam et al teaches a frequency of 1MHz (p.3384, left col., ln.11), and specifically teaches amplitudes of 0.3 V/μm and 1.0 V/μm (e.g.: p.3378 – Abstract; p.3378, right col., lns.21-25; Fig 9).

Relevant to the limitations of claims 3 and 13, Namasivayam et al teaches separation of electrodes by a distance of 20 μm, which is a distance such that no convection is induced in the solution (e.g. p.3384, left col. ln.7 – right col. ln.2).

Relevant to the limitations of claim 4, Namasivayam et al teaches dielectrophoretic migration of the nucleic acid toward the first electrode (e.g.: Fig 5; Fig 9; p.3378, right col., lns.12-28; p.3383 – Effect of electric field).

Relevant to the limitations of claim 11, Namasivayam et al teaches fixing an end of the nucleic acid to the first electrode (e.g.: p.3382, left col., lns.6-20; Fig 9).

Namasivayam et al does not specifically teach the stretching of a single stranded nucleic acid (as recited in claim 1), does not specifically recite that the solution in the reaction well is an aqueous solution (as recited in claim 1) comprising pure water (as reited in claim 12), and does not specifically teach an amplitude of 1.2 V/μm.

However such limitations were well known in the art at the time the invention was made.

Lee et al teaches the manipulation of nucleic acids in electric fields. Relevant to the limitations of claims 1 and 12, Lee teaches separation of single-stranded DNA (ssDNA, as required by claim 1) in a stretched form in pure water (which is an aqueous solution, as require by claim 1 and 12) for deposition of the ssDNA onto electrodes (p.731, left col.) Relevant to the limitations of claim 2, Lee et al teaches that the frequency of the AC electric field was 5MHz (i.e. high frequency) and the voltage was 0.82V/μm (pg 730, left col.).

In the cited prior art of Namasivayam et al a two electrode system (e.g. Fig 9) is used that is comprised of a straight electrode (i.e. the second electrode) adjacent to an active electrode that is a 5-μm flattened tip (i.e. the first electrode). In the rejection as set forth above the interpretation of the first electrode is that the 5-μm flattened tip is the

first electrode, and as such the first electrode has a smaller surface area than the second electrode. It is noted that in Applicants' Remarks of 02/02/2009 (p.6) Applicants argue that the pointed electrode has a greater surface area than that of a straight electrode. While the Examiner maintains that Namasivayam et al teaches the required surface area limitations of the first and second electrodes, it is also noted that the teachings of Namasivayam et al would also render obvious a system of adjacent electrodes wherein two straight electrodes are used where a first electrode consists only of a smaller 5-μm surface and a second electrode consists of the larger surface as set forth in Fig 9 of the reference. Such a system of electrodes is rendered obvious by the teachings of Namasivayam et al that 5-μm flattened tip can serve as an active electrode adjacent to a larger surface electrode (Fig 9, p.3384 left col. – right col.) and that different electrode sizes increase the electric field gradient at the smaller electrode and induce preferential migration (p.3384, left col.) to provide an additional control factor for stretching (p.3383).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have analyzed the ssDNA of Lee et al using the methods of Namasivayam et al. One would have been motivated to analyze ssDNA based on the assertion of Lee et al regarding the importance of the analysis of interactions including ssDNA (e.g. p.730, right col., lns.1-13). It would have been further obvious to perform the methods of Namasivayam et al specifically with an aqueous solution, as taught by Lee et al, where one would have been motivated to use an

aqueous solution based on the successful analysis of nucleic acids in aqueous solutions as taught by Lee et al.

Regarding the limitations of claim 2, while Namasivayam et al teaches amplitudes of 0.3 V/μm and 1.0 V/μm and Lee et al teaches an amplitude of 0.82V/μm, neither Namasivayam et al nor Lee et al particularly teaches an amplitude of 1.2V/μm or higher.

However, the MPEP teaches "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.).

Therefore, it would have been prima facie obvious to the ordinary artisan and the ordinary artisan would have been motivated to modify the method of Namasivayam et al in view of Lee et al by adjusting the voltage amplitude as part of standard optimization practices in the art.

There is a reasonable expectation of success because it is common practice in the art to adjust the general conditions of an experiment as a routine means of optimization.

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 103 as obvious in view of the teachings of the cited prior art. Applicants arguments have been fully and carefully considered but are not found to be persuasive to withdraw the rejection. Applicants' argument is that Namasivayam et al fails to teach a first electrode that has a smaller surface area than a second electrode. As set forth in the rejection, the Examiner has cited the 5-μm flattened tip of Namasivayam et al as the first electrode, and as such the first electrode has a smaller surface area than the second electrode. Alternatively, the Examiner has set forth that the teachings of Namasivayam et al render obvious a particular adjacent electrode configuration in which two straight electrodes are used where a first electrode consists only of a smaller 5-μm surface and a second electrode consists of the larger surface as set forth in Fig 9 of the reference.

The rejection as set forth is maintained.

Conclusion

2. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Stephen Kapushoc/
Art Unit 1634